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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,305	02/21/2007	David Michalovich	SER-113	6503

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,305	MICHALOVICH ET AL.	
	Examiner	Art Unit	
	JON M. LOCKARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *51-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 51 and 52-58, in so far as they are drawn to polypeptides and fusions thereof, and compositions and kits comprising the same.

Group II, claim(s) 51 and 59-61, in so far as they are drawn to polynucleotides, vectors and host cells comprising the same, and compositions and kits comprising the same.

Group III, claim(s) 51, in so far as it is drawn to a ligand of undisclosed constitution.

Group IV, claim(s) 51 and 62, in so far as they are drawn to antibodies and compositions and kits comprising the same.

Group V, claim(s) 51, in so far as it is drawn to a transgenic organism.

Group VI, claim(s) 63-64, 66-67, and 72, drawn to a method for diagnosing a disease comprising measuring gene expression or activity.

Group VII, claim(s) 65, drawn to a method for diagnosing a disease comprising measuring a ligand-polypeptide complex.

Group VIII, claim(s) 68-71, drawn to a method for diagnosing a disease comprising detecting the presence of a mutation in a nucleic acid.

Group IX, claim(s) 73, in so far as it is drawn to a method for treating a disease comprising administering a polypeptide.

Group X, claim(s) 73, in so far as it is drawn to a method for treating a disease comprising administering a nucleic acid.

Group XI, claim(s) 73, in so far as it is drawn to a method for treating a disease comprising administering a ligand of undisclosed constitution.

Group XII, claim(s) 73, in so far as it is drawn to a method for treating a disease comprising administering an antibody.

Group XIII, claim(s) 74, in so far as it is drawn to a method for monitoring the therapeutic treatment of disease comprising monitoring the expression or activity of a polypeptide or fusion thereof.

Group XIV, claim(s) 74, in so far as it is drawn to a method for monitoring the therapeutic treatment of disease comprising monitoring the expression or activity of a polynucleotide.

Group XV, claim(s) 75, in so far as it is drawn to a method for screening compounds utilizing a polypeptide or fusion thereof.

Group XVI, claim(s) 75, in so far as it is drawn to a method for screening compounds utilizing a polynucleotide.

Group XVII, claim(s) 75, in so far as it is drawn to a method for screening compounds utilizing a transgenic animal.

2. The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to a polypeptide comprising an amino acid sequence that comprises or consists of SEQ ID NO:10; a functional equivalent of an amino acid sequence that comprises or consists of SEQ ID NO:10 or a fragment thereof, said fragment functioning as a biologically active polypeptide and/or has an antigenic determinant in common with said polypeptide; a functional equivalent of an amino acid sequence that comprises or consists of SEQ ID NO:10, wherein said functional equivalent is homologous to the amino acid sequence as recited in SEQ ID NO:10 and is a leucine rich repeat containing polypeptide; or a polypeptide that has greater than 50% sequence identity with the amino acid sequence recited in SEQ ID NO:10. However, since Sun et al. (WO 03/020953 A2, published 13 March 2003) teach a polypeptide set forth as SEQ ID NO:189 that shares 73% sequence identity to SEQ ID NO:10 and comprises a sequence that shares 99.7% sequence identity to amino acid residues 237-870 of SEQ ID NO:10, no special technical feature exists for group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Because the technical feature of Group I is not a special technical feature, and because the technical features of the Groups II-XVII inventions is not present in the Group I claims, unity of invention is lacking. Furthermore, the polypeptides of Group I, the polynucleotides of Group II, the ligands of undisclosed constitution of Group III, the antibodies of Group IV, and the and the transgenic organisms of Group V, are structurally and functionally different chemical compounds, having different structures and activities, or in the case of the transgenic animals an organism, and each of which can be made and used without the other compounds. The methods of Groups VI-XVII

require compounds which are functionally different from each other and each can be made and used without the other. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Further Restriction Within Groups I-XVII

3. Whichever Group is elected, further restriction within the elected Group is required to one of the following: One (1) polypeptide (SEQ ID NO:#) and a single (1) corresponding polynucleotide (SEQ ID NO:#) that encodes it.

4. The individual polypeptides and polynucleotides do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each polynucleotide and polypeptide represents a structurally and functionally different chemical compound from each other, which can be made and used without the other compounds. Moreover, the antibodies and ligands which bind the polypeptide are structurally and functionally different compounds, and the methods of using the compounds are also different methods. Lack of unity is shown because these compounds and methods lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

5. **Applicants are advised that this is not a species election.**

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

7. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao, Ph.D.**, can be reached on **(571) 272-0939**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jon M. Lockard, Ph.D.
August 18, 2008

/Jon M Lockard/
Examiner, Art Unit 1647